AMERICAN ACADEMY OF NEUROLOGY®

Press Release

**EMBARGOED FOR RELEASE UNTIL 12 P.M. ET/6 A.M. HST, TUESDAY, APRIL 12, 2011**

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# Investigational Drug May Reduce Involuntary Movements in People with Parkinson's Disease

**HONOLULU** – Results of the first randomized, placebo-controlled long-term clinical trial show the investigational drug safinamide may reduce dyskinesia or involuntary movements in mid-to-late stage Parkinson's disease. The findings will be presented as late-breaking research at the 63rd Annual Meeting of the American Academy of Neurology, April 9–16, 2011, in Honolulu.

"Our findings over a two-year treatment period suggest that taking safinamide in addition to levodopa and other dopaminergic treatments could help patients who continue to experience tremors and involuntary movement problems," said study author Ravi Anand, MD, a consultant with Newron Pharmaceuticals in Bresso, Italy. "These results are an important step forward in understanding how safinamide impacts patients with severe Parkinson's disease. Symptoms of Parkinson`s disease, motor fluctuations and dyskinesia can greatly affect a person's daily living and quality of life."

For the two-year study, 669 patients with mid-to-late stage Parkinson's disease who were already taking levodopa and other dopaminergic treatments were given 50 or 100 milligrams of safinamide per day or a placebo pill. Scientists tested participant's movement ability using the United Parkinson's disease rating scale that measures activities such as tremor, speech, behavior, mood and daily activities including swallowing, dressing and walking. A specific tool measuring severity of dyskinesia (DRS) was used in addition as primary efficacy endpoint.

At the start of the study, patients who took the 50 milligram dose of safinamide had an average score of 3.9 compared to a score of 3.4 for those taking a placebo pill. Patients who took the 100 milligram dose had an average score of 3.7.

After two years, researchers discovered in a post-hoc analysis that safinamide at 100 milligrams a day on top of taking levodopa reduced dyskinesia, or movement problems, by 24 percent in the one-third of participants who had scored a four or higher on the dyskinesia rating scale at the beginning of the study compared to those taking a placebo. There were no significant differences for people who took the 50 milligram dose.

There were no significant differences in the primary efficacy measure (movement control, i.e., dyskinesia) scores in the overall population. Side effects were comparable among the three treatment groups.

The study was supported by Newron/Merck Serono S.A.-Geneva.

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The American Academy of Neurology, an association of more than 22,500 neurologists and neuroscience professionals, is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a doctor with specialized training in diagnosing, treating and managing disorders of the brain and nervous system such as Alzheimer's disease, stroke, migraine, multiple sclerosis, brain injury, epilepsy and Parkinson's disease.

For more information about the American Academy of Neurology and its upcoming Annual Meeting, visit http://www.aan.com.

**Editor's Note:**
Dr. Anand will be available for media questions during a press conference at 4:30 p.m. ET/10:30 a.m. HST, on Monday, April 11, 2011, in Room 325B of the Hawaii Convention Center in Honolulu. Please contact Rachel Seroka, rseroka@aan.com, to receive conference call information for those reporters covering the press conference off-site.

Dr. Anand is available for advance interviews as well. Please contact Rachel Seroka, rseroka@aan.com, to schedule an advance interview.

To access non-late-breaking abstracts to be presented at the 2011 AAN Annual Meeting, visit http://www.aan.com/go/am11/science. Late-breaking abstracts will not be posted online in advance of the meeting and are embargoed until the date and time of presentation at the AAN Annual Meeting in Honolulu or unless otherwise noted by the Academy's Media and Public Relations Department.

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